REMARKS

The present communication responds to the Office Action mailed April 19, 2004. In that Office Action, the Examiner rejected claims 8-20 of the present application. With this communication, claim 1 is amended to clarify that the access structure is independent, claim 12 is rewritten as independent, claim 15 is amended to clarify that the dialysis probe is implantable, and claims 16 and 17 are amended to correct grammatical errors. New claims 21-23 have been added depending from claim 12. New independent claim 24 and associated dependent claims 25-29 have been added.

Rejection under 35 U.S.C. § 102

Claims 8, 9 and 11-18 were rejected under 35 U.S.C. § 102(b) as being anticipated by Skrabal (U.S. Patent 5,237,993). Specifically, the Examiner asserted that, in figure 16, for example, Skrabal shows a device including an access structure, needle 2, connected to a measuring device that houses a removable and replaceable sensor 10, where the body fluid to be analyzed is supplied to the sensor 10 through the needle to an outlet of the needle connected to an inlet of the body, and insulin is supplied from an outlet of the body to an inlet of the needle and back into the human body. The Examiner argued that, as such, the device is an infusion set. This rejection is traversed for the following reasons.

Skrabal does not disclose an implantable structure with a sensor being arranged on the measuring device outside of the body. An implantable access structure with a sensor arranged on the measuring device outside the body is recited by claim 8. An implanted dialysis probe with a sensor being arranged in the outlet of the dialysis probe, the outlet of the dialysis probe being outside of the body is recited by claim 12. An implantable dialysis probe with a sensor being carried by a portion of a discharge tube lying outside of a patient's body is recited by claim 15. An implanted dialysis probe with a sensor being located outside of the patient's body is recited by claim 24. Figure 16 of Skrabal discloses:

> ... a "glucose pen" with a pen-shaped housing 70 provided with a subcutaneous needle 2 on one end. Inside the housing there is a plunger pump 32 with a reservoir 17 for the perfusion fluid, from which the perfusion fluid may be pumped into the needle or delivered to the collecting vessel 18 by means of the plunger 33 ... the perfusion fluid

> may be delivered in the described manner to the openings 9 of the subcutaneous needle and collected again in vessel 18 through the drainage tube 7 by means of the prevailing suction. As close to the subcutaneous needle as possible the analyzing unit 10 is placed together with the measuring capillary 10' for the substance to be analyzed and for the marker substance or marker variable ... The complete set comprising the reservoir 17 and the collecting vessel 18 for the perfusion fluid and, possible, the analyzing unit 10 should be configured as a one-time set which may be removed from the "glucose pen" after unscrewing the threaded part 75 of the housing 70, and may be replaced by a new set.

Skrabal, column 18, lines 41-57 and column 19, lines 30-35. Skrabal explains that repeated puncturing of the body may be required:

> If the needle is to be inserted into the body repeatedly, the diameter of the needle or catheter should be as small as possible

Skrabal, column 12, lines 55-57.

Thus, Skrabal discloses a glucose pen with a subcutaneous needle at its tip, the needle may be inserted into the body and a plunger actuated to deliver perfusion fluid through the needle, the fluid then being collected through a drainage tube. After the measuring process, the needle may be removed from the body. In Figure 16, Skrabal discloses no portion of a device that is implantable within the body, as explicitly required by claims 8, 12, 15 and 24.

Skrabal does disclose an implantable configuration wherein the *entire* device is implanted in the body. In that configuration, no portion of the device is located outside of the body:

> The entire device may also be configured as an implantable unit, by providing a preformed channel 4 on the surface of the implanted device and by using large portions of the surface as an equilibration area. In such an implantable device the reservoirs 17 and 19 for the perfusion fluid and the drug could be refilled transcutaneously by means of a needle via a septum 57, as shown in Figure 15 ... The skin would have to be punctured only from time to time in order to refill the reservoirs for the perfusion fluid or the drug.

Skrabal, column 18, lines 10-26. Thus, Skrabal does not disclose, for example, locating a sensor outside of the patient's body, as explicitly recited in claims 8, 12, 15 and 24.

While Skrabal discloses both an embodiment wherein the entire structure is non-implantable, including only a needle for insertion into the body, and an embodiment wherein the entire structure is implantable with no portion remaining outside of the body, Skrabal does not

disclose or suggest an embodiment wherein a portion of the structure is implantable and a portion of the structure remains outside of the body. In both embodiments of Skrabal, repeated puncturing of the skin is required. The embodiment of Skrabal wherein a portion of the device (the complete set comprising the reservoir 17, the collecting vessel 18 and possibly the analyzing unit 10) is removable and replaceable is an embodiment wherein no portion of the device is implantable. Skrabal provides no teaching or suggestion of a device wherein a portion of the device is implanted, thus minimizing puncturing of the skin, but wherein another portion of the device, such as the sensor, is easily removed and replaced.

Thus, the applicants respectfully assert that claims 8, 9, 11-18 and 21-29 are patentable over Skrabal. Accordingly, it is respectfully requested that the rejection of claims 8, 9 and 11-18 under 35 U.S.C. § 102(b) as being anticipated by Skrabal be withdrawn.

Rejection under 35 U.S.C.§ 103

Claims 10, 19 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Skrabal in view of Say (U.S. Patent 6,128,519). Specifically, the Examiner asserted that Say shows the same type of device as Skrabal, where there is a check valve 44 for preventing flow of fluid from the sensor back to the needle. The Examiner thus argued that it would have been obvious to modify Skrabal to include such a valve, so as to control the fluid flow and maintain accurate readings. This rejection is traversed for the following reasons.

Say discloses a sensor assembly including a catheter having a catheter sheath adapted for insertion in a patient, and a catheter hub connected to the catheter sheath. An adapter is connected to the catheter hub and includes first and second ports. A first flow line extends between the first port of the adapter and a pump. A sensor is positioned along the first flow line. A second flow line extends from the second port of the adapter to a container for holding a calibration fluid. *Say, column 2, lines 23-31.* Say does not disclose or suggest an implantable structure with a sensor being arranged on the measuring device outside of the body, as required by each of claims 8, 12, 15, and 24 as described above.

As neither Skrabal nor Say disclose or suggest an implantable structure with a sensor being arranged on the measuring device outside of the body, the applicants respectfully assert

that claims 10, 19 and 20 are patentable over Skrabal in view of Say. Accordingly, it is respectfully requested that the rejection of claims 10, 19 and 20 under 35 U.S.C. § 103(a) as being unpatentable over Skrabal in view of Say be withdrawn.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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